

Remarks/Arguments

Reconsideration of the subject application as amended herein is respectfully requested.

Claims 1-13 claims stand rejected as being anticipated by, or obvious over Brown alone or Kuhle in combination with Violante or Garnier. The Applicant respectfully traverses these rejections. The Applicant further traverses the Examiner's position on the objective evidence of unobviousness.

The present invention pertains to pain management during injections. As discussed in the specification, and other submitted materials, pain felt by patients during injections is a major problem in anaesthesiology. The present inventor has discovered that one of the sources of pain during injections is the deflection of the needle, and that this pain can be reduced or prevented if, during the injection process, while the needle is advanced toward an injection site within a soft tissue, it is also rotated to eliminate deflections.

Brown discloses an injection syringe which is advanced into a predetermined position and then two drugs are released in sequence while the needle is turning about its axis thereby forming either a sphere, as seen in Figs. 2 and 3 or two joined spherical portions as seen in Fig. 4 (See also Col. 1, lines 43-52). It is clear from the specification and from these drawings that the needle is only rotated only after it has reached the injection site. The claims clearly recite that in the present invention the needle is advanced and simultaneously rotated. In Brown, the needle is clearly not simultaneously translated and rotated because the plume in Figs. 1-4 would have an elongated cylindrical shape and not a spherical shape.

The examiner has indicated that he is relying on Brown as teaching that it is well known to twist or turn a needle of a syringe while inserting it through tissue. Brown merely mentions that “the usual procedure is to insert the needle by a sharp jab or pushing action. Pressure is exerted to the plunger of the syringe to inject the contents. At times, a turning or twisting action may be employed to cause the needle to enter the tissue more easily or more easily affect removal.” (Col. 1, lines 16-22). This passage indicates that the rotation is performed either when the needle is to enter the tissue or when it is to be removed from the tissue. There is nothing in this passage to indicate that it is known in the prior art to rotate and translate the needle simultaneously. The Applicant further notes that Brown discloses a standard syringe. Certainly it is impossible to jab a syringe and rotate it simultaneously. Moreover, Brown has nothing to do with pain management.

The claims were further rejected as being obvious over Kuhle in view of Violante. Kuhle discloses an injection needle having a very unique tip. The purpose of this tip is to enable a clinician to insert a needle along a curved path to avoid an obstruction. Thus, a person skilled in the art would not find this reference relevant since it has no discussion on pain management. Kuhle does offer two methods of administering an injection which result in an overall straight or linear trajectory for a needle tip. One method (col. 7, lines 1-7) consists of rotating the needle by 360 degrees to thereby cause the deflection force on the needle tip to average out to zero. This suggests that the special tip described in the patent undergoes a curved path but when it has turned 360 degrees its final position is linear with its starting position. Nowhere does this mode of operation limit the needle deflection in between the starting and ending

positions. Moreover, it is clear from the reference that the inventor is completely unaware of the pain caused by the needle deflection.

The second method (col. 7, lines 7-15) is to advance the needle tip in small incremental steps and at the end of each step to rotate the needle by 180 degrees. In this method, the tip moves radially back and forth in a zig-zag fashion. Again, there is no direction given by the reference on how to control the needle tip to control pain.

The Examiner relies on Violante for disclosing the importance of directing the needle tip to the correct site. However, this reference again has no means or discussion on how to provide pain management.

Finally, Garnier states (Col 1, Line 26) that *"This object is achieved by providing the syringe with means for rotating the needle about its axis during the injection process".... "For this reason, it is preferred to cause the needle to oscillate in an angular sense about its axis, thereby avoiding injury or breakage if the needle bends following deflection"*. Garner fails to describe a means toward pain management as it relates to movement of the needle.

The above discussion covers the general concept of reducing or eliminating pain during an injection by applying a bidirectional motion to the injection needle. Another consideration for this concept is that, preferably, during this bidirectional motion, the needle should be advanced at a steady constant rate. As indicated in the specification and the claims (see claims 6 and 23), preferably this rate is in the range of 2-4mm/sec.

The Examiner has rejected claim 6 because, in his view, the rate of advancement is not important. The Applicant disagrees. Maintaining a uniform, consistent advancing rate (such as 2-4mm/sec) while simultaneously rotating is

consistent advancing rate (such as 2-4mm/sec) while simultaneously rotating is important to the method described, as it (1) ensures uniform movement of the needle through the tissue in a consistent manner, (2) provides the reduction/elimination of pain (i.e. pain management) by minimizing/eliminating any inconsistent movements of the needle known to cause stimulation to pain receptor cells within the body. It is stimulation to these pain receptors that result in pain on insertion and movement of a needle.

The use of a consistent (uniform) advance rate (example: 2-4mm/sec) that eliminates/minimizes patient pain perception by providing the least amount of aberrant movement thereby eliminating/minimizing stimulation during movement of the needle that results in pain management from the deliberate, gentle movement of the needle through tissue.

Kuhle makes no mention of the need or importance of advancing rate. Advancing rate is left to be performed arbitrarily, or which could be done erratically or inconsistently causing maximum stimulation of pain receptors producing an uncomfortable and painful experience for the patient.

Brown discusses that "At times, a turning or twisting action may be employed", (Col 2,Line43) "rotating the needle of the syringe 360 degrees or while holding the needle stationary". Brown further teaches that "*jabbing is the usual procedure, but that turning or twisting may be employed at some time*" for the said reason of "*to get an easier entry*". These discussions of needle movements fail to identify the importance or need for consistent (uniform) advance rate as described and claimed herein for pain management.

Violante describes that (Col. 3, Line 56) "The practitioner simultaneously guides the needle so that it penetrates through the mucous membrane", Violante makes no mention to the importance or need of advancing rate, nor a method to provide pain management as it relates to the movement of a needle, as described and claimed herein.

In summary, the claims cover a method of controlling pain during injections that is not disclosed in any of the references. It is respectfully submitted that the subject application is now in condition for allowance. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to the Deposit Account No. 07-1730, Docket No. 3486-018. A duplicate copy of this Communication is attached for that purpose.

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Respectfully submitted,

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